EXAMINER'S AMENDMENT

Applicant's amendments filed on 03/10/2010 in response to the final office action dated 02/19/2010 has been entered.

Claims 1, 6-13, 15-23, 27-29, 33-34 are pending and under consideration. Claims 2-5, 24-26, 30-32, 35-62 are canceled.

Applicant's arguments filed on 03/10/2010; 11/30/2009; 10/13/2008; ; 10/01/2007 have been found persuasive.

The rejection of claims 1, 6-13, 15-21, 23, 27-29, 33-34 under 35 U.S.C. 112, first paragraph, for lack of enablement over the full scope, is withdrawn.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas Howerton on 3/24/2010.

The application has been amended as follows:

Claim amendments:

1. A transgenic caprine whose genome comprises a~~n exogenous~~ nucleic acid encoding at least one transgenic polypeptide, comprising a secretion signal, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcription control region, wherein said control region comprises a bovine salivary gland protein promoter selected from the group consisting of

bSP30a and bSP30b, wherein said polypeptide is expressed and secreted in the saliva of the transgenic caprine.

6. The caprine of Claim 1, wherein said polypeptide ~~comprises~~ is an active form.

7. The caprine of Claim 1, wherein said polypeptide ~~comprises~~ is a proactive form.

9. The caprine of Claim 1, wherein said transgenic polypeptide is produced at a level of 5.0 mg/ml saliva.

11. The caprine of Claim 1, wherein said transgenic polypeptide ~~comprises a specific activity relative to that~~ has the activity of the naturally occurring polypeptide.

12. The caprine of Claim 1, wherein the activity of the ~~said~~ transgenic polypeptide is ~~comprises a specific activity ranging~~ from 25% to 95% ~~relative to~~ of the activity ~~that~~ of the naturally occurring polypeptide.

13. Canceled.

15. Canceled

17. The caprine of Claim 16, wherein said salivary gland pair comprises a parotid gland pair.

18. Canceled

20. A method, comprising: a) providing; i) a transgenic caprine whose genome comprises an ~~exogenous~~ nucleic acid encoding at least one transgenic polypeptide, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcriptional control region, wherein said control region comprises a bovine salivary gland protein promoter selected from the group consisting of bSP30a and bSP30b, said caprine ~~capable of~~ producing saliva, wherein said polypeptide is produced in said saliva ~~and is collected from a salivary gland duct~~; ii) a flexible tubing to collect said saliva; b) making a surgical incision in said salivary gland duct; ~~and~~ c) cannulating said duct with said tubing; and d) collecting said saliva.

21. Canceled

23. The method of Claim 20~~21~~, further comprising the step of isolating said polypeptide from said saliva.

29. A method, comprising: a) providing; i) a first DNA sequence comprising 5' cis-acting expression signals, said first DNA sequence being derived from a first salivary gland secretory protein gene, said first gene comprising a bovine salivary gland protein promoter selected from the group consisting of bSP30a and bSP30b; ii) a second DNA sequence encoding a polypeptide of interest and a region encoding an operable secretion signal, said secretion signal being derived from a second salivary gland secretory protein gene; and iii) a third DNA sequence comprising termination and 3' regulatory signals, said third DNA sequence being derived from a third salivary gland secretory protein gene, wherein said first, second, and third salivary gland secretory protein genes are not necessarily different; b) joining said first, second, and third DNA sequences in operable linkage effective for salivary gland expression and saliva-

specific expression of said polypeptide of interest to create a transgene construct; c) cloning said transgene construct to produce a vector; d) microinjecting said vector into a caprine zygote ~~embryo~~; and e) transferring the zygote produced in step d) into a pseudopregnant female caprine of the same species, thereby producing a transgenic caprine whose genome comprises a transgenic polypeptide transgene ~~capable of engendering~~ which results in expression and secretion of said polypeptide in saliva of said caprine.

The following is an examiner's statement of reasons for allowance: The prior art does not teach or suggest a transgenic caprine whose genome comprises a nucleic acid encoding at least one transgenic polypeptide, comprising a secretion signal, said nucleic acid operably linked to a salivary gland-specific cis-acting 5' transcription control region, wherein said control region comprises a bovine salivary gland protein promoter selected from the group consisting of bSP30a and bSP30b, wherein said polypeptide is expressed and secreted in the saliva of the transgenic caprine. Support for the amendment of a secretion signal is found in the specification [0177]. Support for the amendment, wherein said polypeptide is expressed and secreted in the saliva of the transgenic caprine is found in the declaration of Dr. Jeffery Erickson under 37 CFR & 1.132 filed on 10/01/2007. .

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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